

### REMARKS / ARGUMENTS

Claims 74 and 78-81 are pending in this application. Claims 61-73 and 75-77 have been canceled without prejudice.

The Examiner has requested that the applicant disclose co-pending applications which may present double patenting issues. The pending claims were rejected for various double patenting issues.

Applicants submit herewith a copy of pending claims in related applications. Applicants also submit herewith a docket of related applications.

Claims 78 and 79 were rejected as being indefinite. The claims have been amended to obviate this rejection.

Claims 74 and 77-79 were rejected as being anticipated by Cain et al ('657). Claims 74-76 were rejected as being anticipated by Sherman et al. ('280). Claims 74 and 76-79 were rejected as being anticipated by Hissong ('531). Claims 77-79 were rejected as being obvious over Sherman in view of Hissong. Claims 80 and 81 were rejected as being obvious over Sherman or Hissong in view of Marcus ('484).

### Discussion

Amended independent claim 74 is allowable over the cited art since the cited art does not disclose or suggest "a plurality of ablating elements which each emit focused ultrasound energy" and "a control system coupled to the ablating elements, the control system controlling activation of the ablating elements and adapted to automatically change the frequency of the ablating elements when ablating the same tissue structure, each ablating element being activated to ablate tissue at a first frequency for a plurality of first time periods and to ablate the same tissue at a second frequency, which is different than the first frequency, for a plurality of second time periods."

The cited art does not disclose or suggest a plurality of ablating elements which each emit focused ultrasound let alone in combination with a control system which

automatically activates the ablating elements at a first frequency for a first plurality of time periods and at a second frequency for a second plurality of time periods as claimed.

Dependent claims 78-81 are allowable since they depend from allowable independent claim 74 and because they recite independently patentable features.

CONCLUSION

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-412-3322.

Respectfully submitted,

September 26, 2003  
Date

  
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## EPICOR, INC.

Docket of related cases with claims attached.

Matter No.	Appln. No.	Filing Date	Title
002-C1	09/606,742	06/29/2000	SURGICAL SYSTEM AND PROCEDURE FOR TREATMENT OF MEDICALLY REFRACTORY ATRIAL FIBRILLATION
002-C3	10/171,411	06/12/2002	DEVICE AND METHOD FOR FORMING A LESION
002-C4	10/171,390	06/12/2002	DEVICE AND METHOD FOR FORMING A LESION
002-C5	10/172,732	06/14/2002	DEVICE AND METHOD FOR FORMING A LESION
004-C5	10/171,389	06/12/2002	DEVICE AND METHOD FOR FORMING A LESION
004-C6	10/232,963	08/30/2002	APPARATUS AND METHOD FOR DIAGNOSIS AND THERAPY OF ELECTROPHYSIOLOGICAL DISEASE
004-C7	10/232,964	08/30/2002	APPARATUS AND METHOD FOR DIAGNOSIS AND THERAPY OF ELECTROPHYSIOLOGICAL DISEASE
005-CP	09/507,336	02/18/2000	APPARATUS AND METHOD FOR ABLATING TISSUE
006	09/614,991	07/12/2000	APPARATUS AND METHOD FOR ABLATING TISSUE
006-C1	09/698,357	10/27/2000	APPARATUS AND METHOD FOR ABLATING TISSUE
006-C4	09/699,215	10/27/2000	APPARATUS AND METHOD FOR ABLATING TISSUE
007	09/884,435	06/19/2001	METHODS AND DEVICES FOR ABLATION
007-C1	10/008,904	12/05/2001	METHODS AND DEVICES FOR ABLATION
007-C2	10/010,409	12/05/2001	METHODS AND DEVICES FOR ABLATION
007-C3	10/006,064	12/05/2001	METHODS AND DEVICES FOR ABLATION
007-C4	10/008,997	12/05/2001	METHODS AND DEVICES FOR ABLATION
007-C5	10/006,088	12/05/2001	METHODS AND DEVICES FOR ABLATION
010	10/077,470	02/15/2002	METHODS AND DEVICES FOR ABLATION
010-C1	10/238,821	09/10/2002	METHODS AND DEVICES FOR ABLATION

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on February 13, 2003

By: \_\_\_\_\_

Nikia M. McMillion

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of )

DR. JAMES L. COX, *et al.* )

Examiner: D. J. ISABELLA

Application No.: 09/606,742 )

Art Unit: 3738

Filed: June 29, 2000 )

For: SURGICAL SYSTEM AND )  
PROCEDURE FOR TREATMENT )  
OF MEDICALLY REFRACTORY )  
ATRIAL FIBRILLATION )

AMENDMENT

Commissioner for Patents  
Washington, D.C. 20231

Sir:

In response to the Office Action mailed September 13, 2002, please amend this application as follows:

IN THE CLAIMS:

Please cancel claim 48 without prejudice and amend claims 26, 34 and 36 as indicated below.

Please substitute the following clean, unmarked copy of all pending claims for the claims presently in the application file:

26. (Amended) A method of forming an elongate ablation to electrically isolate one part of the heart from another part of the heart, comprising the steps of:

providing an ablation device having an elongate ablating portion;  
forming an opening in the patient's pericardium;  
introducing the ablation device through the opening in the pericardium;  
positioning the elongate ablating portion in contact with a portion of the patient's heart;  
ablating tissue with the elongate ablating portion; and  
forming a lesion extending from the pulmonary vein isolation lesion to the annulus of the mitral valve.

27. The method of claim 26, wherein:  
the ablating step is carried out to form a pulmonary vein isolation lesion which electrically isolates at least one of the pulmonary veins.

28. The method of claims 26 or 27, wherein:  
the ablating step is carried out with the elongate ablating portion contacting an epicardial surface.

29. The method of claim 27, further comprising the step of:  
forming a lesion extending from the pulmonary vein isolation lesion to the annulus of the mitral valve.

30. The method of claim 27, wherein:  
the ablating step is carried out with the pulmonary vein isolation lesion being formed by creating a first lesion adjacent to two of the pulmonary veins.

31. The method of claim 30, wherein:  
the ablating step is carried out with the pulmonary vein isolation lesion being formed by creating a second lesion near the other two pulmonary veins.

32. The method of claim 31, wherein:  
the ablating step is carried out with the pulmonary vein isolation lesion being formed by creating a third lesion which connects the first and second lesions.

33. The method of claim 32, wherein:

the ablating step is carried out with the third lesion being formed by two lesions.

34. (Amended) The method of claim 27, further comprising the step of:

inserting the ablation device into the patient's heart through a penetration in the patient's heart.

35. The method of claim 34, wherein:

the positioning step is carried out with the elongate ablating portion being in contact with an epicardial surface.

36. (Amended) The method of claim 34, wherein:

the inserting step is carried out with the ablation device extending through a hemostatic seal in an atrial wall.

37. The method of claim 36, wherein:

the inserting step is carried out with the hemostatic seal being a purse-string suture.

38. The method of claim 26, wherein:

the providing step is carried out with a plurality of ablation devices, each of the ablation devices having at least one elongate ablating portion; and  
the ablating step is carried out using the plurality of ablation devices.

39. The method of claim 38, wherein:

the plurality of ablation devices have different shapes.

40. The method of claim 39, wherein:

the providing step is carried out with each of the ablation devices being shaped to engage a predetermined surface of the heart.

41. The method of claim 40, wherein:

the providing step is carried out with the predetermined surface of the heart being an interior wall of the heart.

42. The method of claim 41, wherein:

the providing step is carried out with the predetermined surface of the heart being an interior wall of an atria chamber.

43. The method of claim 26, further comprising the steps of:

moving the elongate ablating portion to another position; and  
forming another elongate ablation after the moving step.

44. The method of claim 26, further comprising the step of:

forming a series of elongate ablations which cooperate with one another to treat atrial fibrillation.

45. The method of claim 26, wherein:

the providing step is carried out with the ablating element being a cryosurgical element.

46. The method of claim 26, wherein:

the providing step is carried out with the ablating element being an ablating element selected from the group consisting of cryosurgical, RF ablation, ultrasound, microwave, laser, chemical agent, biological agent, light-activated agent, laser ablation and resistance heating ablation.

47. The method of claim 26, wherein:

the providing step is carried out with the elongate ablating surface extending a distance of at least about 7 times to about 30 times an outer diameter.

48. Canceled

49. The method of claim 26, further comprising the step of:  
measuring a temperature of a wall of the heart on a side opposite the elongate  
ablating portion.

50. The method of claim 49, wherein:  
the measuring step is carried out to determine when the ablating step is complete.

51. The method of claim 26, wherein:  
the providing step is carried out with the elongate ablating surface being  
malleable.

Please add new claims 52-81 as follows:

52. (new) A method of forming an elongate ablation to electrically isolate one  
part of the heart from another part of the heart, comprising the steps of:

providing an ablation device having an elongate ablating portion, the device  
having a first jaw and a second jaw which are movable toward and away from one another to  
clamp a cardiac structure;

forming an opening in the patient's pericardium;

introducing the ablation device through the opening in the pericardium;

positioning the elongate ablating portion in contact with a portion of the patient's  
heart; and

ablating tissue with the elongate ablating portion.

53. (new) (new) The method of claim 52, wherein:  
the ablating step is carried out to form a pulmonary vein isolation lesion which  
electrically isolates at least one of the pulmonary veins.

54. (new) The method of claims 52 or 53, wherein:  
the ablating step is carried out with the elongate ablating portion contacting an  
epicardial surface.



55. (new) The method of claim 52, further comprising the step of:  
inserting the ablation device into the patient's heart through a penetration in the  
patient's heart.

56. (new) The method of claim 55, wherein:  
the positioning step is carried out with the elongate ablating portion being in  
contact with an epicardial surface.

57. (new) The method of claim 55, wherein:  
the inserting step is carried out with the ablation device extending through a  
hemostatic seal in an atrial wall.

58. (new) The method of claim 57, wherein:  
the inserting step is carried out with the hemostatic seal being a purse-string  
suture.

59. (new) The method of claim 52, wherein:  
the providing step is carried out with a plurality of ablation devices, each of the  
ablation devices having at least one elongate ablating portion; and  
the ablating step is carried out using the plurality of ablation devices.

60. (new) The method of claim 59, wherein:  
the plurality of ablation devices have different shapes.

61. (new) The method of claim 59, wherein:  
the providing step is carried out with each of the ablation devices being shaped to  
engage a predetermined surface of the heart.

62. (new) The method of claim 61, wherein:

the providing step is carried out with the predetermined surface of the heart being an interior wall of the heart.

63. (new) The method of claim 61, wherein:

the providing step is carried out with the predetermined surface of the heart being an interior wall of an atria chamber.

64. (new) The method of claim 52, further comprising the steps of:

moving the elongate ablating portion to another position; and  
forming another elongate ablation after the moving step.

65. (new) The method of claim 52, further comprising the step of:

forming a series of elongate ablations which cooperate with one another to treat atrial fibrillation.

66. (new) The method of claim 52, wherein:

the providing step is carried out with the ablating element being a cryosurgical element.

67. (new) The method of claim 52, wherein:

the providing step is carried out with the ablating element being an ablating element selected from the group consisting of cryosurgical, RF ablation, ultrasound, microwave, laser, chemical agent, biological agent, light-activated agent, laser ablation and resistance heating ablation.

68. (new) The method of claim 52, wherein:

the providing step is carried out with the elongate ablating surface extending a distance of at least about 7 times to about 30 times an outer diameter.

69. (new) The method of claim 52, further comprising the step of:

measuring a temperature of a wall of the heart on a side opposite the elongate ablating portion.

70. (new) The method of claim 69, wherein:  
the measuring step is carried out to determine when the ablating step is complete.

71. (new) A method of forming an elongate ablation to electrically isolate one part of the heart from another part of the heart, comprising the steps of:

providing an ablation device having an elongate ablating portion;  
forming an opening in the patient's pericardium;  
introducing the ablation device through the opening in the pericardium;  
positioning the elongate ablating portion in contact with a portion of the patient's heart; and  
ablating tissue with the elongate ablating portion, the ablating step is carried out with the pulmonary vein isolation lesion being formed by creating a first lesion adjacent to two of the pulmonary veins.

72. (new) The method of claim 71, wherein:  
the ablating step is carried out to form a pulmonary vein isolation lesion which electrically isolates at least one of the pulmonary veins.

73. (new) The method of claims 71 or 72, wherein:  
the ablating step is carried out with the elongate ablating portion contacting an epicardial surface.

75. (new) The method of claim 71, wherein:  
the ablating step is carried out with the pulmonary vein isolation lesion being formed by creating a second lesion near the other two pulmonary veins.

76. (new) The method of claim 75, wherein:

the ablating step is carried out with the pulmonary vein isolation lesion being formed by creating a third lesion which connects the first and second lesions.

77. (new) The method of claim 76, wherein:

the ablating step is carried out with the third lesion being formed by two lesions.

78. (new) The method of claim 71, wherein:

the positioning step is carried out with the elongate ablating portion being in contact with an epicardial surface.

79. (new) The method of claim 71, further comprising the step of:

inserting at least part of the ablation device into the patient's heart through a penetration in the patient's heart.

80. (new) The method of claim 79, wherein:

the inserting step is carried out with the ablation device extending through a hemostatic seal in an atrial wall.

81. (new) The method of claim 79, wherein:

the inserting step is carried out with the hemostatic seal being a purse-string suture.

003-002 C3

Appln. No. 10/171411

Cox et al.

Filed: June 12, 2002

Title: DEVICE AND METHOD FOR FORMING A LESION

21. A method of forming an elongate ablation to treat cardiac arrhythmia, comprising the steps of:

- providing an ablation device having a first jaw, a second jaw and at least one ablating portion on the first jaw, the first jaw being movable relative to the second jaw to clamp cardiac tissue therebetween;

- forming an opening in a patient's body;

- forming an opening in the pericardium;

- moving the ablation device through the openings in the patient's body and pericardium;

- clamping a portion of the patient's heart between the first and second jaws, the at least one ablating portion being positioned to form an elongate lesion in the patient's heart to electrically isolate tissue; and

- ablating tissue with the at least one ablating portion to form the elongate lesion.

22. The method of claim 21, wherein:

- the clamping step is carried out by inserting at least one of the first and second jaws into the patient's heart so that the ablation device clamps the portion of the patient's heart between an endocardial surface and an epicardial surface.

23. The method of claim 22, wherein:

- the clamping step is carried out by using a purse-string suture to maintain hemostasis around the jaw which is inserted into the patient's heart.

24. The method of claim 21, wherein:

- the providing step is carried out with the first jaw pivoting relative to the second jaw.

25. The method of claim 21, wherein:

- the providing step is carried out with the ablating portion extending along a length of the first jaw.

003-002-C4

Appln. No. 10/171,390

COX et al.

Filed: June 12, 2002

Title: DEVICE AND METHOD FOR FORMING A LESION

21. A tissue ablation system for treating atrial arrhythmia in a patient, comprising:  
a circumferential ablation member which is adapted to be delivered to a position relative to a circumferential region of tissue at a location where a pulmonary vein extends from an atrium in the patient, the circumferential ablation member having an ablation element which is adapted to ablate a substantial portion of the circumferential region of tissue without delivery of an ablative fluid to the tissue.
22. The system of claim 21, wherein the ablation element comprises a light emitting ablation element.
23. The system of claim 21, wherein the ablation element comprises a cryogenic ablation element.
24. The system of claim 21, wherein the ablation element comprises an ultrasound ablation element.
25. The system of claim 21, wherein the ablation element comprises a microwave ablation element.
26. The system of claim 21, wherein the ablation element comprises a thermal ablation element.
27. The system of claim 21, wherein the ablation element is adapted to be coupled to and actuated by an ablation actuator.
28. The system of claim 21, further comprising an elongate body with a proximal end portion and a distal end portion, wherein the circumferential ablation member is located at least in part along the distal end portion, and the elongate body is adapted to deliver the circumferential ablation member to the desired position.
29. The system of claim 28, further comprising an expandable member located at least in part along the distal end portion and which is adapted to be positioned within and expanded to engage the pulmonary vein while the ablation element is ablatively coupled to the circumferential region of tissue.
30. The system of claim 21, further comprising a delivery system cooperating with the circumferential ablation member and which is adapted to deliver the circumferential ablation member to the desired position.
31. The system of claim 21, wherein the ablation element is adapted to ablate a substantial portion of the circumferential region of tissue without delivery of electrical current.
32. A method for treating atrial arrhythmia in a patient, comprising:  
delivering an ablation element within an epicardial space adjacent to a circumferential region of tissue at a location where a single pulmonary vein extends from an atrium in the patient; and  
ablating a substantial portion of the circumferential region of tissue with the ablation element.
33. The method of claim 32, further comprising ablating the substantial portion of the circumferential region of tissue by optically coupling a light emitting ablation element to the circumferential region of tissue.
34. The method of claim 32, further comprising ablating the substantial portion of the circumferential region of tissue by cryogenically coupling a cryogenic ablation element to the circumferential region of tissue.
35. The method of claim 32, further comprising ablating the substantial portion of the circumferential region of tissue by ultrasonically coupling an ultrasound ablation element to the circumferential region of tissue.
36. The method of claim 32, further comprising ablating the substantial portion of the circumferential region of tissue by inductively coupling a microwave ablation element to the circumferential region of tissue.
37. The method of claim 32, further comprising ablating the substantial portion of the circumferential region of tissue by thermally coupling a thermal ablation element to the circumferential region of tissue.

38. The method of claim 32, further comprising:  
ablating the circumferential region of tissue while surrounding the circumferential region of tissue with the ablation element within the epicardial space while actuating the ablation element with an ablation actuator.

39. The method of claim 32, wherein the circumferential region of tissue has a circumference, and further comprising ablating the circumferential region of tissue by translating the ablation element along the circumference while actuating the ablation element by an ablation actuator.

40. The method of claim 32, wherein the circumferential region of tissue has a circumference, and further comprising ablating the circumferential region of tissue along the entire circumference with the ablation element.

003-002-C5

Appln. No. 10/172,732

COX et al.

Filed: June 14, 2002

Title: DEVICE AND METHOD FOR FORMING A LESION

21. A tissue ablation device system for ablating a circumferential region of tissue at a location where a single pulmonary vein extends from an atrium in a patient, comprising:

an ablation member with a contact member which is adapted to substantially contact the circumferential region of tissue, and also with an ablation element which is adapted to be ablatively coupled to the circumferential region of tissue when the circumferential ablation member is positioned at the location; and  
a delivery assembly that cooperates with the circumferential ablation member and that is adapted to deliver the circumferential ablation member to the location.

22. The tissue ablation device system of claim 21, wherein the contact member comprises a body that is adapted to have a looped geometry which substantially contacts the circumferential region of tissue.

23. The tissue ablation device system of claim 22, wherein  
the contact member is adapted to be positioned in a collapsed geometry within a delivery passageway of a delivery catheter and to be delivered through the delivery passageway and into the atrium; and  
the contact member is adjustable to the looped geometry when the contact member is positioned externally of the delivery passageway.

24. The tissue ablation device system of claim 22, wherein the looped geometry is sized to engage the pulmonary vein.

25. The tissue ablation device system of claim 21, wherein the contact member is adjustable from a first configuration, which is adapted to be delivered through a delivery passageway of a delivery catheter and into the atrium, to a second configuration which is adapted to contact the circumferential region of tissue.

26. The tissue ablation device system of claim 21, wherein  
the delivery assembly comprises a delivery catheter with a proximal end portion and a distal end portion and a delivery passageway extending between a distal port along the distal end portion and a proximal port located proximally of the distal port; and  
the ablation member is adapted to be advanced through the delivery passageway and into the atrium through the distal port.

27. The tissue ablation device system of claim 21, wherein the delivery assembly comprises an elongate body with a proximal end portion and a distal end portion; and  
the ablation member is located at least in part along the distal end portion of the elongate body.

28. The tissue ablation device system of claim 27, wherein the contact member is located at least in part along the distal end portion of the elongate body.

29. The tissue ablation device system of claim 27, wherein the delivery assembly further comprises a tracking member that is located at least in part along the elongate body and that is adapted to slideably engage a guide member seated within the pulmonary vein and to track over the guide member in order to position the circumferential ablation member along the location.

30. The tissue ablation device system of claim 29, further comprising a pulmonary vein guide member that is adapted to be seated within the pulmonary vein and also to be slideably engaged and tracked by the tracking member.

31. The tissue ablation device system of claim 21, wherein the ablation element comprises at least one electrode that is adapted to couple to an electrical current source.



32. The tissue ablation device system of claim 21, wherein the ablation element comprises a plurality of electrodes that are located at least in part along the contact member and that are adapted to couple to an electrical current source.

33. The tissue ablation device system of claim 21, wherein the ablation element comprises a cryogenic ablation element.

34. The tissue ablation device system of claim 21, wherein the ablation element comprises an ultrasound ablation element.

35. The tissue ablation device system of claim 21, wherein the ablation element comprises a light emitting ablation element.

36. The tissue ablation device system of claim 21, wherein the ablation element comprises a microwave ablation element.

37. The tissue ablation device system of claim 21, wherein the ablation element comprises a thermal ablation element.

38. The tissue ablation device system of claim 21, wherein the ablation element comprises a chemical fluid ablation element.

39. A tissue ablation device system for ablating a circumferential region of tissue at a location where a pulmonary vein extends from an atrium in a patient, comprising:

a delivery member with a proximal end portion, a distal end portion, a longitudinal axis, and a fluid passageway extending along at least the proximal end portion and which is adapted to be fluidly coupled to a fluid source at a proximal fluid port located along the proximal end portion; and

an expandable member located along the distal end portion with a working length along the longitudinal axis which is adjustable between a radially collapsed position and a radially expanded position wherein the working length has a first portion, a second portion, and an intermediate portion between the first and second portions along the longitudinal axis and which in the radially expanded position has an expanded outer diameter that is sufficient to engage the circumferential region of tissue, wherein in the radially expanded position the system is adapted to allow a volume of fluid within the fluid passageway to be ablatively coupled to only a circumferential area surrounding the intermediate portion, whereby engaging the circumferential region of tissue with the intermediate portion the circumferential region of tissue may be positioned within the circumferential area such that the volume of fluid may be ablatively coupled to the circumferential region of tissue.

40. A tissue ablation device system as in claim 39, further comprising an ablation electrode which is adapted to be electrically coupled to an electrical current source and also to the fluid passageway when the volume of fluid comprises an electrically conductive medium, wherein the intermediate portion is adapted to allow the ablation electrode to be ablatively coupled to the circumferential area via an electrical current flowing at least in part through the electrically conductive medium.

41. A tissue ablation device system as in claim 20, wherein the ablation electrode is located at least in part within the fluid passageway.

42. A tissue ablation device system as in claim 39, wherein the intermediate portion is adapted to allow the volume of fluid to pass from within the fluid passageway and into the circumferential area.

43. A tissue ablation device system as in claim 39, further comprising a pressurizeable source of ablative fluid that is adapted to be fluidly coupled to the fluid passageway via the proximal port, wherein the intermediate portion is adapted to allow a volume of the ablative fluid within the fluid passageway to be ablatively coupled to only the circumferential area.

44. A tissue ablation device system as in claim 39, wherein the expandable member further comprises a balloon wall with an outer surface along the working length, and also comprises an outer wall having an inner surface

which is disposed around and circumscribes the balloon wall along the intermediate portion;  
the fluid passageway comprises an interior space formed at least in part between the inner and outer surfaces, and the circumferential area surrounds the outer wall along the intermediate portion; and  
the system is adapted to allow the volume of fluid within the interior space to be ablatively coupled to the circumferential area through the outer wall.

45. A tissue ablation device system as in claim 39, wherein the expandable member further comprises an expandable balloon with a balloon wall constructed at least in part from a porous membrane along the first, second, and intermediate portions;

the balloon wall defines at least in part an interior space that forms at least a portion of the fluid passageway;

a first shield cooperates with the porous membrane to substantially prevent the volume of fluid within the interior space from being ablatively coupled to a first adjacent area surrounding the first portion;

a second shield cooperates with the porous membrane to substantially prevent the volume of fluid within the interior space from being ablatively coupled to a second adjacent area surrounding the second portion; and

the balloon wall along the intermediate portion is substantially unshielded such that the volume of fluid within the interior space may be ablatively coupled to the circumferential area through at least one pore provided along the porous membrane.

46. The tissue ablation device system of claim 39, further comprising an ultrasound ablation element which cooperates with the expandable member and which in the radially expanded condition is adapted to be ultrasonically coupled to the circumferential area.

47. The tissue ablation device system of claim 39, further comprising an electrode ablation element which cooperates with the expandable member and which in the radially expanded condition is adapted to be electrically coupled to the circumferential area.

48. The tissue ablation device system of claim 39, further comprising a thermal ablation element which cooperates with the expandable member and which in the radially expanded condition is adapted to be thermally coupled to the circumferential area.

49. The tissue ablation device system of claim 39, further comprising a cryogenic ablation element which cooperates with the expandable member and which in the radially expanded condition is adapted to be cryogenically coupled to the circumferential area.

50. The tissue ablation device system of claim 39, further comprising a light emitting ablation element which cooperates with the expandable member and which in the radially expanded condition is adapted to be optically coupled to the circumferential area.

51. The tissue ablation device system of claim 39, further comprising a microwave ablation element which cooperates with the expandable member and which in the radially expanded condition is adapted to be ablatively coupled to the circumferential area.

52. The tissue ablation device system of claim 39, further comprising a chemical ablation element which cooperates with the expandable member and which in the radially expanded condition is adapted to be chemically coupled to the circumferential area.

53. A tissue ablation device system for ablating a circumferential region of tissue at a location where a pulmonary vein extends from an atrium, comprising:

a circumferential ablation member with an ablation element which is adapted to be ablatively coupled to the circumferential region of tissue when the circumferential ablation member is positioned along the location; and

a delivery assembly cooperating with the circumferential ablation member and which is adapted to deliver the circumferential ablation member to the location, wherein the delivery assembly comprises a delivery member having a proximal end portion and a distal end portion with a tracking member which is adapted to slidably engage a guide member seated within the pulmonary vein and to track over the guide member such that the

circumferential ablation member may be positioned at the location.

54. The tissue ablation device system of claim 53, wherein the tracking member further comprises a tracking passageway extending between a distal port along the distal end portion of the delivery member and a proximal port located along the delivery member proximally of the distal port, the tracking passageway being adapted to receive and slideably engage the guide member through the distal and proximal ports and along the tracking passageway.

55. The tissue ablation device system of claim 54, wherein the proximal port is located along the distal end portion of the delivery member.

56. The tissue ablation device system of claim 54, wherein the proximal port is located along the proximal end portion of the delivery member and is adapted to be positioned externally of the patient when the circumferential ablation member is positioned at the location.

57. The tissue ablation device system of claim 56, further comprising a pulmonary vein guide member which is adapted to be seated within the pulmonary vein and to be moveably engaged and tracked by the tracking member.

58. The tissue ablation device system of claim 57, wherein the pulmonary vein guide member comprises a guidewire which is adapted to have a shaped, steerable distal tip.

59. The tissue ablation device system of claim 57, wherein the guidewire has an outer diameter from about 0.018 inches to about 0.035 inches.

60. The tissue ablation device system of claim 53, wherein the delivery assembly further comprises at least one guiding catheter which has an internal passageway which is adapted to slideably receive the circumferential ablation member and the delivery member and also to deliver the circumferential ablation member into the atrium.

61. The tissue ablation device system of claim 53, wherein the ablation element further comprises an electrode ablation element.

62. The tissue ablation device system of claim 53, wherein the ablation element further comprises an ultrasound ablation element.

63. The tissue ablation device system of claim 53, wherein the ablation element further comprises a thermal ablation element.

64. The tissue ablation device system of claim 53, wherein the ablation element further comprises a light emitting ablation element.

65. The tissue ablation device system of claim 53, wherein the ablation element further comprises a microwave ablation element.

66. The tissue ablation device system of claim 53, wherein the ablation element further comprises a chemical ablation element.

67. A tissue ablation device system for ablating a circumferential region of tissue at a location where a pulmonary vein extends from an atrium, comprising:  
a circumferential ablation member with an ablation element which is adapted to ablatively couple to the circumferential region of tissue when the circumferential ablation member is positioned along the location; and  
a delivery member with a proximal end portion and a distal end portion, wherein the circumferential ablation member is located at least in part along the distal end portion and is adapted to be delivered to the location at least in part with the delivery member,  
wherein the system is adapted to allow a volume of blood to flow from the pulmonary vein, across the location, and into the atrium when the circumferential ablation member is positioned along the location and the

ablation element is ablatively coupled to the circumferential region of tissue.

68. The tissue ablation device system of claim 67, further comprising a perfusion member cooperating with the circumferential ablation member and also with the delivery member and having a perfusion passageway extending between a distal port located distally of the circumferential ablation member and a proximal port located proximally of the circumferential ablation member,

wherein the perfusion passageway is adapted to allow blood to flow through the distal port, along the perfusion passageway, and out the proximal port while the ablation element is ablatively coupled to the circumferential region of tissue.

69. The tissue ablation device assembly as in claim 67, wherein the circumferential ablation member additionally includes an expandable member cooperating with the ablation element and which is adapted to substantially engage the circumferential region of tissue when the ablation element is ablatively coupled to the circumferential region of tissue.

70. The tissue ablation device assembly of claim 67, wherein the ablation element further comprises an electrode ablation element.

71. The tissue ablation device assembly of claim 67, wherein the ablation element further comprises an ultrasound ablation element.

72. The tissue ablation device assembly of claim 67, wherein the ablation element further comprises a thermal ablation element.

73. The tissue ablation device assembly of claim 67, wherein the ablation element further comprises a light emitting ablation element.

74. The tissue ablation device assembly of claim 67, wherein the ablation element further comprises a microwave ablation element.

75. The tissue ablation device assembly of claim 67, wherein the ablation element further comprises a chemical ablation element.--

003-004 C5

Appln. No. 10/171,389

Vaska et al.

Filed: June 12, 2002

Title: DEVICE AND METHOD FOR FORMING A LESION

26. A tissue ablation system for treating atrial arrhythmia in a patient, comprising:  
a circumferential ablation member which is adapted to be delivered to a position relative to a circumferential region of tissue at a location where a pulmonary vein extends from an atrium in the patient, the circumferential ablation member having an ablation element which is adapted to ablate a substantial portion of the circumferential region of tissue without delivery of an ablative fluid to the tissue.
27. The system of claim 26, wherein the ablation element comprises a light emitting ablation element.
28. The system of claim 26, wherein the ablation element comprises a cryogenic ablation element.
29. The system of claim 26, wherein the ablation element comprises an ultrasound ablation element.
30. The system of claim 26, wherein the ablation element comprises a microwave ablation element.
31. The system of claim 26, wherein the ablation element comprises a thermal ablation element.
32. The system of claim 26, wherein the ablation element is adapted to be coupled to and actuated by an ablation actuator.
33. The system of claim 26, further comprising an elongate body with a proximal end portion and a distal end portion, wherein the circumferential ablation member is located at least in part along the distal end portion, and the elongate body is adapted to deliver the circumferential ablation member to the desired position.
34. The system of claim 8, further comprising an expandable member located at least in part along the distal end portion and which is adapted to be positioned within and expanded to engage the pulmonary vein while the ablation element is ablatively coupled to the circumferential region of tissue.
35. The system of claim 26, further comprising a delivery system cooperating with the circumferential ablation member and which is adapted to deliver the circumferential ablation member to the desired position.

36. The system of claim 26, wherein the ablation element is adapted to ablate a substantial portion of the circumferential region of tissue without delivery of electrical current.
37. A method for treating atrial arrhythmia in a patient, comprising:  
delivering an ablation element within an epicardial space adjacent to a circumferential region of tissue at a location where a single pulmonary vein extends from an atrium in the patient; and  
ablating a substantial portion of the circumferential region of tissue with the ablation element.
38. The method of claim 37, further comprising ablating the substantial portion of the circumferential region of tissue by optically coupling a light emitting ablation element to the circumferential region of tissue.
39. The method of claim 37, further comprising ablating the substantial portion of the circumferential region of tissue by cryogenically coupling a cryogenic ablation element to the circumferential region of tissue.
40. The method of claim 37, further comprising ablating the substantial portion of the circumferential region of tissue by ultrasonically coupling an ultrasound ablation element to the circumferential region of tissue.
41. The method of claim 37, further comprising ablating the substantial portion of the circumferential region of tissue by inductively coupling a microwave ablation element to the circumferential region of tissue.
42. The method of claim 37, further comprising ablating the substantial portion of the circumferential region of tissue by thermally coupling a thermal ablation element to the circumferential region of tissue.
43. The method of claim 37, further comprising:  
ablating the circumferential region of tissue while surrounding the circumferential region of tissue with the ablation element within the epicardial space while actuating the ablation element with an ablation actuator.
44. The method of claim 37, wherein the circumferential region of tissue has a circumference, and further comprising ablating the circumferential region of tissue by translating the ablation element along the circumference while actuating the ablation element by an ablation actuator.
45. The method of claim 37, wherein the circumferential region of tissue has a circumference, and further comprising ablating the circumferential region of tissue along the entire circumference with the ablation element.

003-004 C6

Appln. No. 10/232,963

Vaska et al.

Filed: August 30, 2002

Title: APPARATUS AND METHOD FOR DIAGNOSIS AND THERAPY OF  
ELECTROPHYSIOLOGICAL DISEASE

Claims 1 – 21 follow.

**WHAT IS CLAIMED IS:**

1 1. A method of positioning an ablating surface against tissue, comprising the  
2 steps of:  
3 providing an ablating device having a first ablating portion, a second ablating  
4 portion and an end;  
5 introducing the ablating device into the space between the pericardium and the  
6 epicardium;  
7 positioning the end of the ablating element in the transverse pericardial sinus  
8 so that the first ablating surface is positioned in the transverse pericardial sinus; and  
9 moving the second ablating portion toward the pulmonary veins after the  
10 positioning step; and  
11 ablating the tissue adjacent to the pulmonary veins with the first and second  
12 ablating portions.

1 2. The method of claim 1, wherein:  
2 the ablating step is carried out with the first ablating portion extending  
3 adjacent to the pericardial reflection extending between the right superior and left  
4 superior pulmonary veins.

1 3. The method of claim 1, wherein:  
2 the moving step is carried out with the second ablating portion extending adjacent the  
3 pericardial reflection between the left inferior and right interior pulmonary veins.

1 4. The method of claim 1, wherein:  
2 the providing step is carried out with the ablating device having a proximal  
3 portion and a distal portion.

1 5. The method of claim 4, wherein:  
2 the anchoring step is carried out with an expandable device on the ablating device, the  
3 expandable device being expanded to resist movement of the expandable device  
4 during the moving step.



1 6. The method of claim 5, wherein:  
2 the anchoring step is carried out with the expandable device being an inflatable  
3 balloon.

1 7. The method of claim 4, wherein:  
2 the moving step is carried out by advancing a member into the proximal  
3 portion which shapes the proximal portion.

1 8. The method of claim 7, wherein:  
2 the moving step is carried out with the member having a shape which moves the  
3 proximal portion nearer to the pulmonary veins.

1 9. The method of claim 7, wherein:  
2 the moving step is carried out with the member being malleable.

1 10. The method of claim 9, wherein:  
2 the moving step is carried out with the member having a predetermined shape.

1 11. A method of forming ablations to electrically isolate a structure of a patient's  
2 heart, comprising the steps of:  
3 providing a first ablating device having a first ablating element;  
4 introducing the first ablating device into a space between the pericardium and  
5 epicardium;  
6 positioning a part of the first ablating device against a structure of the patient's  
7 heart;  
8 moving another part of the ablating device around the structure of the patient's  
9 heart after the positioning step; and  
10 ablating tissue to create a lesion with the first ablating element.

1 12. The method of claim 11, wherein:

2           the positioning step is carried out with the structure is a structure selected from  
3           the group consisting of the pulmonary veins, inferior vena cava, superior vena cava,  
4           aorta, pulmonary artery, atrial appendage and pericardial reflections.

1   13.    The method of claim 11, wherein:

2           the positioning step is carried out with the part of the ablating device which  
3           engages the structure having a curved shape.

1   14.    The method of claim 13, wherein:

2           the ablating step is carried out with the curved part of the ablating device  
3           ablating around a portion of a vessel.

1   15.    The method of claim 13, wherein:

2           the ablating step is carried out with the curved part having a radius of  
3           curvature of 4 to 30 mm.

1   16.    The method of claim 11, wherein:

2           the providing step is carried out by providing a second ablating device, the  
3           second ablating device having a second ablating element; and  
4           the ablating step is carried out by ablating tissue with the first and second  
5           ablating elements.

1   17.    A method of creating a continuous lesion in tissue, comprising the steps of:

2           providing an ablating device having an ablating element;  
3           introducing the ablating device into a space between the epicardium and  
4           pericardium;  
5           ablating tissue after the introducing step to create a first lesion;  
6           moving the ablating device after the ablating step;  
7           positioning the ablating device at a location so that a second lesion formed  
8           with the ablating element will be continuous with the first lesion;  
9           ablating tissue with the ablating element to create the second lesion continuous  
10          with the first lesion.

1 18. The method of claim 17, wherein:  
2 the providing step is carried out with the ablating device having a locating  
3 device positioned adjacent the ablating element, the locating device locating a position  
4 of the first lesion.

1 19. The method of claim 17, wherein:  
2 the providing step is carried out with the ablating device having first and  
3 second electrodes.

1 20. The method of claim 19, further comprising the step of:  
2 measuring relative electrogram amplitude between the first and second  
3 electrodes.

1 21. The method of claim 19, further comprising the step of:  
2 sending an electrical impulse with one of the electrodes.

003-004 C7

Appln. No. 10/232,964

Vaska et al.

Filed: August 30, 2002

Title: APPARATUS AND METHOD FOR DIAGNOSIS AND THERAPY OF  
ELECTROPHYSIOLOGICAL DISEASE

Claims 1 – 25 follow.

**WHAT IS CLAIMED IS:**

1     1.     A system for ablating tissue from a location between the epicardium and the  
2     pericardium, comprising:  
3             a first device capable of being advanced into the pericardial space;  
4             a second device slidably coupled to the first device, the second device having  
5     an expandable device; and  
6             an ablating device mounted to at least one of the first and second devices, the  
7     ablating device being configured to create a lesion.

1     2.     The system of claim 1, wherein:  
2             the ablating device is mounted to the second device.

1     3.     The system of claim 1, wherein:  
2             the ablating device is mounted to the first device.

1     4.     The system of claim 1, further comprising:  
2             a sensor coupled to at least one of the first and second devices, the sensor  
3     being positioned adjacent the ablating device to detect a location of a previously  
4     formed ablation for proper positioning of the ablating device.

1     5.     The system of claim 1, wherein:  
2             the first device has an anchor which holds the first device at a location  
3     between the pericardium and epicardium.

1     6.     A method of forming a continuous ablation across a pericardial reflection  
2     when ablating tissue from a position between the pericardium and epicardium, the  
3     method comprising the steps of:  
4             providing a first ablating device having a first ablating element and a second  
5     ablating device having a second ablating element, the first ablating device having a  
6     penetrating element;

7           introducing the first and second ablating devices into the space between the  
8 pericardium and the epicardium;  
9           penetrating a pericardial reflection with the penetrating element.

1    7.     The method of claim 6, wherein:  
2           the providing step is carried out with the first and second ablating devices  
3 interlocking.

1    8.     The method of claim 7, further comprising the step of:  
2           interlocking the first and second ablating devices after the penetrating step.

1    9.     A method of ablating tissue from a location between the epicardium and the  
2 pericardium, comprising:  
3           providing an ablating device having an ablating element;  
4           introducing the ablating device into the pericardial space;  
5           forming a first lesion with the ablating element;  
6           moving the ablating device; and  
7           forming a second lesion continuous with the first lesion.

1    10.    The method of claim 9, wherein:  
2           the forming and moving steps are carried out to form a lesion adjacent the  
3 pulmonary veins.

1    11.    The method of claim 9, wherein:  
2           the providing step is carried out with the ablating device being slidably  
3 coupled to a first device;  
4           the method further comprising the steps of advancing the first device ahead of  
5 the ablating device; and  
6           the moving step being carried out by slidably moving the ablating device along the  
7 first device.

1    12.    The method of claim 11, wherein:

2           the providing step is carried out with the first device having an anchor to hold  
3   a part of the device at a location in the pericardial space.

1   13.    The method of claim 12, wherein:

2           the providing step is carried out with the anchor being a device selected from  
3   the group consisting of a suction port, tine, and an expandable member.

1   14.    The method of claim 9, wherein:

2           the ablating device has means for locating the first lesion;  
3           the method further comprising the steps of locating the first lesion with the  
4   locating means before forming the second lesion.

1   15.    A method of creating a lesion from a location in the pericardial space,  
2   comprising the steps of:

3           providing a first device and a second device slidably coupled to the first  
4   device, the second device having an expandable member mounted thereto, at least one  
5   of the first and second devices having an ablating element;  
6           introducing a first and second devices into the pericardial space;  
7           ablating tissue to form a first lesion with the ablating element;  
8           moving at least one of the first and second devices relative to the other; and  
9           forming a second lesion after the moving step.

1   16.    The method of claim 15, wherein:

2           the providing step is carried out with the ablating element being mounted to  
3   the first device.

1   17.    The method of claim 16, wherein:

2           the providing step is carried out with the first device having a plurality of  
3   ablating elements; and  
4           the forming step is carried out with another of the ablating elements on the  
5   first device.

1   18.    The method of claim 16, wherein:

2           the providing step is carried out with at least one of the first and second  
3 devices having means for locating the first lesion; and  
4           the method further comprising the step of locating the first lesion with the  
5 locating means before the forming step.

1   19.    A method of forming a lesion from a location in the pericardial space,  
2 comprising the steps of:  
3           introducing a first ablating device into the pericardial space, the ablating  
4 device having an ablating element;  
5           advancing the first ablating device to a pericardial reflection;  
6           penetrating the pericardial reflection with the first ablating device; and  
7           forming a first lesion with the ablating element.

1   20.    The method of claim 19, further comprising the step of:  
2           interlocking a first part of the first ablating device with a second part of the  
3 first ablating device after the penetrating step.

1   21.    The method of claim 19, further comprising the steps of:  
2           introducing a second ablating device into the pericardial space; and  
3           interlocking the first and second ablating devices after the penetrating step.

1   22.    A method of forming a lesion beneath a pericardial reflection, comprising the  
2 steps of:  
3           providing a first device having an emitter and a second device having a sensor;  
4           positioning the first device on a side of a pericardial reflection;  
5           emitting energy from the emitter after the positioning step; and  
6           moving the second device to a position on the opposite side of the pericardial  
7 reflection using the sensor which senses the energy emitted by the emitter.

1   23.    The method of claim 22, further comprising the step of:  
2           penetrating the pericardial reflection with at least one of the first and second  
3 devices.



- 1 24. The method of claim 23, further comprising the step of:  
2 interlocking the first and second devices after the penetrating step.
- 1 25. The method of claim 22, further comprising the step of:  
2 forming a lesion beneath the pericardial reflection with at least one of the first  
3 and second devices.

003-005-CP

Appln. No. 09/507,336

ANDERSON et al.

Filed: February 18, 2000

Title: APPARATUS AND METHOD FOR ABLATING TISSUE

27. A device for ablating cardiac tissue, comprising:  
a body;  
an ablating element coupled to the body;  
a sensor positioned to measure a parameter at tissue ablated by the ablating element; and  
a control system coupled to the sensor and the ablating element, the control system receiving parameter measurements from the sensor, the control system being operably coupled to the ablating element and delivering energy to the ablating element in response to the parameter measurements to create a lesion in the tissue.
28. The device of claim 27, wherein:  
the sensor is a temperature sensor; and  
the control system receives temperature change measurements over a period of time.
29. The device of claim 28, wherein:  
the control system delivers energy to the ablating element until the temperature sensor measures a temperature below a threshold temperature.
30. The device of claim 28, wherein:  
the control system delivers energy to the ablating element for a selected period of time while maintaining the temperature of a near surface of the tissue between 0-80°C.
31. The device of claim 28, further comprising:  
a plurality of ablating elements; and  
a plurality of temperature sensors, wherein at least two temperature sensors correspond to each ablating element; and  
the control system receives the temperature change measurements from the at least two temperature sensors for each ablating element.

32. The device of claim 31, wherein:  
each of the plurality of temperature sensors corresponds to one of the ablating elements; and  
the control system delivers energy to at least one of the ablating elements for which the corresponding temperature sensor measures a lowest temperature.
33. The device of claim 27, wherein:  
the body has a locking mechanism for locking one part of the body to another part of the body to form a closed loop.

003-006  
Serial No. 09/614,991  
Pless et al.  
Filed July 12, 2000  
Apparatus and Method for Ablating Tissue

140. (Currently amended) A method of ablating a cardiac tissue from an epicardial location, comprising the steps of:  
    providing an ablating device having a first ultrasound emitting element and a second ultrasound emitting element, each of the first and second ultrasound emitting elements emitting focused ultrasound having a focal length of 2-20 mm;  
    positioning the ablating device against an epicardial surface overlying a cardiac tissue structure to be ablated;  
    activating the first ultrasound emitting element at a first frequency to produce focused ultrasound having the focal length of 2-20 mm, the focused ultrasound ablating a cardiac tissue structure; and  
    activating the second ultrasound emitting element at a second frequency, different from the first frequency, to produce focused ultrasound having the focal length of 2-20 mm to ablate the cardiac tissue structure.

141. (Currently amended) The method of claim 140, further comprising the step of:  
    moving the ablating device so that the activating steps are carried out to ablate the same tissue.

142. (Currently amended) The method of claim 140, wherein:  
    the activating steps are carried out to ablate different cardiac tissue.

143. (Currently amended) The method of claim 140, further comprising:  
    characterizing a portion of cardiac tissue; and  
    selecting at least one of the first and second ultrasound emitting elements to ablate the portion of cardiac tissue based on the characterizing step.

144. (Previously added) A method of ablating a cardiac tissue from an epicardial location, comprising the steps of:  
    providing an ablating device having a body with a first ultrasound emitting element and a second ultrasound emitting element, the first and second ultrasound emitting elements both producing focused ultrasound, the first and second ultrasound emitting elements producing focused ultrasound having different focal lengths relative to the body;  
    positioning the ablating device at an epicardial location;  
    activating the first ultrasound emitting element to ablate cardiac tissue; and  
    activating the second ultrasound emitting element.

145. (Previously added) The method of claim 144, wherein:  
the providing step is carried out with the first and second ultrasound emitting  
elements being movable along the body; and  
the positioning step is carried out by positioning the body along a desired ablation  
path.

146. (Previously added) The method of claim 145, further comprising the step of:  
moving the first and second ultrasound emitting elements along the body.

147. (Previously added) The method of claim 145, further comprising the step of:  
positioning the body at a selected location on the epicardial surface to create an  
elongate lesion using the first and second ultrasound emitting elements; and  
moving the first and second ultrasound emitting elements after the positioning step.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on January 21, 2003.

By: \_\_\_\_\_

Erica L. Canonizado

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

BENJAMIN PLESS et al.

Application No.: 09/698,357

Filed: October 27, 2000

For: APPARATUS AND METHOD  
FOR ABLATING TISSUE

Examiner: M. PEFFLEY

Art Unit: 3739

AMENDMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Please enter the following preliminary amendment in this application.

IN THE CLAIMS:

Please cancel claims 1-25, 31, 33, 34 and 40-63 and add new claims 115-129 as follows:

—115. (New) A method of ablating cardiac tissue from an epicardial location, comprising the steps of:

providing an ablating device having an ultrasound emitting element;

positioning the ablating device in contact with a location outside the patient's heart overlying a cardiac tissue structure to be ablated;

activating the ultrasonic emitting element at a first frequency to produce focused ultrasound energy which is directed at the tissue structure, the ultrasound emitting element being activated for a number of discrete time periods at the first frequency; and

activating the ultrasound emitting element for a second period of time at a second frequency which is different than the first frequency, the second period of time occurring after the number of discrete time periods.

116. (New) The method of claim 115, wherein:

the activating steps are carried out with the first period of time being shorter than the second period of time.

117. (New) The method of claim 115, wherein:

the activating steps are carried out with the first period of time being less than 1 second.

118. (New) The method of claim 115, wherein:

the activating step is carried out by activating the ultrasound emitting element at a third frequency different than the first and second for a third period of time, the third period of time occurring after the number of discrete time periods and the second period of time.

119. (New) The method of claim 115, wherein:

the activating step is carried out with the first frequency being about 2-7 MHz and the second frequency being from 2-14 MHz.

120. (New) The method of claim 115, wherein:

the providing step is carried out with the ablating device producing focused energy having a focal length of 2 to 20 mm.

121. (New) The method of claim 115, further comprising the step of:

approximating a temperature using the ultrasound emitting element.

122. (New) The method of claim 115, further comprising the step of:

assessing the adequacy of contact between tissue and the device.

123. (New) The method of claim 115, further comprising the step of:

measuring a blood flow velocity with the ultrasound emitting element.

124. (New) The method of claim 115, further comprising the step of:

determining a tissue layer thickness using the ultrasound emitting element.

125. (New) The method of claim 124, wherein:

the determining step is carried out with the tissue layer being a tissue layer between a near surface and a far surface.

126. (New) The method of claim 115, further comprising the step of:

moving the ultrasound beam after the activating step.

127. (New) The method of claim 126, wherein:

the moving step is carried out with the ultrasound beam being rotated.

128. (New) The method of claim 126, wherein:

the moving step is carried out by moving the ultrasound emitting element.

129. (New) The method of claim 126, wherein:

the moving step is carried out with the ultrasound emitting element being tilted.—

### **REMARKS**

Claims 115-129 are pending in this application. Claims 1-25, 31, 33, 34 and 40-63 have been canceled. Applicants submit that new claims 115-129 read on the elected species.

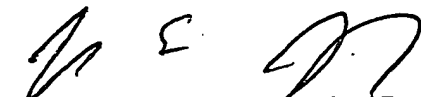
The Examiner requested a listing of related applications with similar disclosure or relevant claims. Applicants submit herewith a listing of related applications. Applicants note that atty docket nos. 003-006, 003-006C2, 003-006C3, and 003-006c4 all have similar disclosures to the present application.

Claims 40-63 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 09/699,215. Applicants submit herewith a terminal disclaimer to obviate any such rejection over the pending claims which are directed to the same elected species.

### **CONCLUSION**

If the Examiner believes a telephone conversation would expedite prosecution of this application, he is invited to telephone the undersigned at 415-412-3322.

Respectfully submitted,



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003-006-C4

Appln. No. 09/699,215

PLESS et al.

Filed: October 27, 2000

Title: APPARATUS AND METHOD FOR ABLATING TISSUE

1. A method of ablating cardiac tissue, comprising the steps of:  
providing an ablating device having an ultrasonic transducer, the device emitting focused ultrasound which is focused in at least one dimension;  
positioning the ablating device in contact with cardiac tissue; and  
activating the ultrasonic transducer to direct the focused ultrasound into the cardiac tissue, the activating step is carried out by activating the ultrasonic transducer for a first period of time at a first frequency and a second period of time at a second frequency which is different than the first frequency and occurs after the first period of time.
2. The method of claim 1, wherein:  
the activating step is carried out to electrically isolate one part of the heart from another part of the heart.
3. The method of claim 1, wherein:  
the providing and activating steps are carried out with the focused ultrasound being focused along a focal axis and diverging when viewed perpendicular to the focal axis.
4. The method of claim 1, further comprising the step of:  
moving a focus of the focused ultrasound relative to the cardiac tissue.
5. The method of claim 4, wherein:  
the moving step is carried out to move the focus closer to a near surface of the cardiac tissue.
6. The method of claim 1, wherein:  
the providing step is carried out so that at least 90% of the focused ultrasound passes within a focus area defined by a focal length of about 2 to 20 mm and an angle of about 10 to 170 degrees when viewed along a focal axis.

7. The method of claim 1, wherein:  
the providing step is carried out with the focused energy being emitted by a concave surface.

8. The method of claim 7, wherein:  
the providing step is carried out with the concave surface having a focal length of 2-20 mm.

9. The method of claim 9, wherein:  
the providing step is carried out with the focused energy having a focal length of 2 to 12 mm.

26. A method of ablating cardiac tissue with ultrasound comprising the steps of:

creating an opening in a patient's chest;  
providing an ablating device which emits focused ultrasound having a focus in at least one direction;  
introducing the ablating device through the opening in the patient's chest;  
positioning the ablating device in contact with a cardiac tissue structure to be ablated, the cardiac tissue structure having a near wall and a far wall; and  
operating the ablating device at a frequency and a power to direct the ultrasonic energy into the tissue structure for a number of discrete time periods; and  
changing at least one of the frequency and location of the focus relative to the tissue and activating the ablating device to ablate the cardiac tissue structure for another period of time.

115. The method of claim 1, wherein:  
the activating step is carried out by changing the frequency to accumulate energy closer to a near surface of the tissue.

116. The method of claim 115, wherein:  
the activating step is carried out with the frequency being increased from a first frequency to a second frequency, the activating step being carried out at the first frequency for a number of discrete periods of time.

117. The method of claim 1, wherein:  
the providing step is carried out with the ultrasonic transducer producing the focused ultrasound having a focal length of 2-20mm.

118. The method of claim 1, further comprising the step of:  
assessing contact between the ablating device and the tissue structure.

119. The method of claim 1, wherein:  
assessing contact between the ablating device and the tissue structure by measuring the electrical impedance.

120. The method of claim 1, further comprising the step of:  
measuring a tissue thickness using ultrasound energy delivered by the ablating device.

121. The method of claim 1, further comprising the step of:  
measuring a fat thickness using ultrasound energy delivered by the ablating device.

122. The method of claim 1, wherein:  
the activating step is carried out with the ablating element being activated at the first frequency for a number of discrete time periods.

123. The method of claim 1, wherein:  
the activating step is carried out by activating the ultrasonic transducer at a third frequency different than the first and second.

124. The method of claim 1, wherein:  
the activating step is carried out with the first frequency being about 2-7 MHz and the second frequency being from 2-14 MHz.

125. The method of claim 1, further comprising the step of:  
measuring a blood flow velocity with the ultrasonic transducer.

126. The method of claim 1, further comprising the step of:  
determining a tissue layer thickness using the ultrasound transducer.

127. The method of claim 1, wherein:  
the determining step is carried out with the tissue layer being a tissue layer  
between a near surface and a far surface.

128. The method of claim 1, further comprising the step of:  
moving an ultrasonic beam emitted by the ultrasound transducer after the  
activating step.

129. The method of claim 128, further comprising the step of:  
tilting the ultrasonic beam.

130. The method of claim 26, wherein:  
the changing step is carried out with the frequency increasing.

131. The method of claim 26, wherein:  
the providing step is carried out with the ablating device producing focused  
ultrasound, wherein the focused ultrasound has a focal length of 2-20mm.

132. The method of claim 26, further comprising the step of:  
assessing contact between the ablating device and the tissue structure.

133. The method of claim 26, further comprising the step of:  
assessing contact between the ablating device and the tissue structure by  
measuring the electrical impedance.

134. The method of claim 26, further comprising:  
measuring a tissue thickness using ultrasound energy delivered by the ablating  
device.

135. The method of claim 26, further comprising the step of:  
measuring a fat thickness using ultrasound energy delivered by the ablating  
device.

136. The method of claim 26, wherein:  
the activating step is carried out with the ablating device being activated at a first  
frequency for a number of discrete time periods.

137. The method of claim 26, wherein:  
the changing step is carried out by activating the ablating device at a frequency of  
2-14 MHz.

138. The method of claim 26, wherein:  
the activating step is carried out at a first frequency of 2-7 MHz; and  
the changing step is carried out at a second frequency of 2-14 MHz.

139. The method of claim 26, further comprising the step of:  
measuring a blood flow velocity with ultrasound energy delivered by the ablating  
device.

140. The method of claim 26, further comprising the step of:  
determining a tissue layer thickness using ultrasound energy delivered by the  
ablating device.

141. The method of claim 26, further comprising the step of:  
moving an ultrasonic beam emitted by the ablating device after the activating  
step.

142. The method of claim 26, further comprising the step of:  
tilting an ultrasonic beam emitted by the ablating device after the activating step.

143. A method of ablating cardiac tissue to form an elongate lesion to treat a cardiac arrhythmia, comprising the steps of:

- providing an ablating device having a plurality of ablating elements, the plurality of ablating elements each emitting focused ultrasound, the focused ultrasound being focused in at least one direction and having a focal length of 2-20mm;

- forming an opening in a patient's chest;

- introducing the ablating device through the opening in the patient's chest;

- positioning the ablating device against an epicardial surface overlying a cardiac tissue structure to be ablated, the cardiac structure having a near wall and a far wall; and

- activating the plurality of ablating elements each for a number of discrete periods of time, the ablating element emitting focused ultrasound into the cardiac tissue structure to ablate the cardiac tissue structure to treat the cardiac arrhythmia.

144. The method of claim 143, wherein:

- the positioning step is carried out with the plurality of ablating elements extending around the pulmonary veins on the epicardial surface.

145. The method of claim 143, wherein:

- the positioning step is carried out with the plurality of ablating elements being angled relative to the epicardial surface to at least partially direct the focused ultrasound toward an adjacent ablating element.

146. The method of claim 143, wherein:

- changing a characteristic of the ablating device and activating the ablating device to produce focused ultrasound which accumulates energy closer to the near wall as compared to the activating step.

147. The method of claim 146, wherein:

- the changing step is carried out with the frequency increasing.

148. The method of claim 143, further comprising the step of:

- assessing contact between the ablating device and the tissue structure.

149. The method of claim 143, wherein:  
assessing contact between the ablating device and the tissue structure by  
measuring the electrical impedance.

150. The method of claim 143, further comprising:  
measuring a tissue thickness using ultrasound energy delivered by the ablating  
device.

151. The method of claim 143, further comprising the step of:  
measuring a fat thickness using ultrasound energy delivered by the ablating  
device.

152. The method of claim 143, wherein:  
the activating step is carried out with at least one of the ablating elements being  
activated at a first frequency for a number of discrete time periods.

153. The method of claim 152, wherein:  
the activating step is carried out with the at least one ablating element being  
activated at a second frequency different than the first frequency.

154. The method of claim 153, wherein:  
the activating step is carried out with the first frequency being about 2-7 MHz  
and the second frequency being from 2-14 MHz.

155. The method of claim 143, further comprising the step of:  
moving an ultrasonic beam emitted by the ablating device after the activating  
step.

156. The method of claim 143, further comprising the step of:  
tilting an ultrasonic beam emitted by the ablating device after the activating  
step.

003-007

Appln. No. 09/884,435

John W. Sliwa et al.

Filed: June 19, 2001

Title: METHODS AND DEVICES FOR ABLATION

8. A method of ablating tissue, comprising the steps of:  
providing an ablating device and a cover, the ablating device having a bottom surface, the cover being spaced apart from the bottom surface to define a fluid cavity, the fluid cavity containing a fluid; positioning the cover against a tissue surface;  
moving the cover away from the bottom surface so that the bottom surface is exposed and positioned adjacent the tissue surface, the flowable material conforming to the shape of the tissue surface and being positioned between the bottom surface of the ablating device and the tissue surface; and ablating the tissue after the moving step.

9. The method of claim 8, wherein:  
the positioning step is carried out with the tissue surface being an epicardial surface.

10. The method of claim 8, wherein:  
the moving step is carried out by moving the cover while substantially maintaining the position of the ablating device.

11. The method of claim 8, wherein:  
the providing step is carried out with the cover having a removable tip.

12. The method of claim 8, wherein:  
the providing step is carried out with the flowable material having a boiling temperature of at least 120 degrees C.

13. The method of claim 8, wherein:  
the providing step is carried out with the flowable material being selected from the group consisting of PEG and glycerine.

14. The method of claim 8, wherein:  
the providing step is carried out with the ablating device having a plurality of ablating elements.

15. The method of claim 8, wherein:  
the providing and moving steps are carried out with the ablating device forming a closed loop.



16. The method of claim 15, wherein:  
the providing and moving steps are carried out with the ablating device forming a closed loop around the pulmonary veins; and the ablating step is carried out to form an ablation around the pulmonary veins.

003-007 C1

Appln. No. 10/008,904

John W. Sliwa et al.

Filed: December 5, 2001

Title: METHODS AND DEVICES FOR ABLATION

29. A method of ablating tissue from an epicardial location, comprising the steps of: providing an ablating device having a tip; advancing the ablating device through a space between the epicardium and pericardium; removing the tip of the ablating device; and ablating tissue with the ablating device.

30. The method of claim 29, further comprising the step of: forming a closed loop with the ablating device after the removing step.

31. The method of claim 29, wherein: the advancing step is carried out with the ablating device having a plurality of ablating elements.

32. The method of claim 29, wherein: ablating step is carried out to form an ablation around the pulmonary veins.

33. The method of claim 29, wherein: the providing step is carried out with the tip having a length of at least two inches and being free of ablating elements.

34. The method of claim 33, wherein: the providing step is carried out with the tip having a length of at least four inches.

35. A method of forming an ablation from an epicardial location, comprising the steps of: creating a liquid environment around a patient's heart; positioning an ablating device against an epicardial location of the patient's heart; and ablating tissue from the epicardial location while the ablating device is contained within the liquid environment.

36. The method of claim 35, wherein: the creating step is carried out by at least partially filling the pericardial space with the liquid to create the liquid environment around the patient's heart.

37. The method of claim 35, wherein: the ablating step is carried out with the ablating device being submerged within the liquid.

38. The method of claim 35, wherein:

the creating step is carried out with the liquid environment being contained by the pericardium.

39. The method of claim 35, wherein:  
the ablating step is carried out with the ablating device having an ablating element which uses RF, ultrasound, laser, cold or microwave.

40. The method of claim 35, wherein:  
the creating step is carried out with the pericardium being incised to create an opening, the fluid environment having an exposed free surface of the liquid.

41. The method of claim 35, wherein:  
the creating step is carried out with the ablating device passing through a penetration in the pericardium.

42. A method of ablating tissue, comprising the steps of:  
providing an ablating device having a convex contact surface;  
positioning the convex contact surface adjacent to an epicardial surface;  
ablating the epicardial tissue after the positioning step.

43. The method of claim 42, wherein:  
the providing step is carried out with the ablating device comprising an ultrasonic transducer.

44. The method of claim 43, wherein:  
the providing step is carried out with the convex surface being formed by an element mounted to the ultrasonic transducer.

45. The method of claim 44, wherein:  
the providing step is carried out with a membrane forming the convex surface.

46. The method of claim 45, wherein:  
the providing step is carried out with the membrane partially defining a cavity containing a fluid.

47. The method of claim 42, wherein:  
the providing step is carried out with the ablating device having a plurality of ablating elements.

48. The method of claim 42, wherein:  
the providing and moving steps are carried out with the ablating device forming a closed loop around the heart.

49. The method of claim 48, wherein:  
the providing and moving steps are carried out with the ablating device forming a closed loop around the pulmonary veins; and

the ablating step is carried out to form an ablation around the pulmonary veins.

50. An ablating device for ablating tissue, comprising:  
a body;  
an ablating element coupled to the body;  
a membrane extending over at least part of the ablating element, the membrane being spaced apart from the ablating element to form a fluid cavity; and  
the fluid cavity containing a fluid.
51. The ablating device of claim 50, further comprising:  
a fluid source coupled to the fluid inlet for circulating the fluid through the fluid cavity.
52. The ablating device of claim 51, further comprising:  
a heat exchanger having an inlet which receives the fluid and an outlet which returns the fluid to the fluid cavity.
53. The ablating device of claim 50, wherein:  
the membrane forms a convex contact surface.
54. The ablating device of claim 50, wherein:  
the membrane forms the convex contact surface with fluid pressure.
55. The ablating device of claim 50, wherein:  
the membrane permits some of the fluid to pass therethrough to wet the target tissue with the fluid.
56. The ablating device of claim 50, wherein:  
the membrane extends over more than one ablating element.
57. An ablating device for ablating tissue, comprising:  
a body;  
an ablating element coupled to the body;  
a flexible skirt surrounding at least a portion of the ablating element;  
the fluid cavity containing a fluid.
58. The ablating device of claim 57, further comprising:  
a fluid delivery channel which delivers fluid to the fluid cavity.
59. The ablating device of claim 57, wherein:  
the body has a contact surface on a bottom side, the contact surface being convex.
60. A method of ablating tissue from an epicardial location using a device according to claims 51-59.

003-007 C2

Appln. No. 10/010,409

John W. Sliwa et al.

Filed December 5, 2001

Title: METHODS AND DEVICES FOR ABLATION

(Please note: the following claims will be renumbered in an official amendment.)

61. (currently amended) A method of ablating cardiac tissue, comprising the steps of: providing an ablating device having an ultrasonic transducer, the device emitting focused ultrasound which is focused in at least one dimension, the providing step being carried out so that at least 90% of the focused ultrasound passes within a focus area defined by a focal length of about 2 to 20 mm and an angle of about 10 to 170 degrees when viewed along a focal axis;

positioning the ablating device in contact with cardiac tissue; and activating the ultrasonic transducer to direct the focused ultrasound into the cardiac tissue.

62. (previously added) The method of claim 61, wherein: the activating step is carried out to electrically isolate one part of the heart from another part of the heart.

63. (previously added) The method of claim 61, wherein: the providing and activating steps are carried out with the focused ultrasound being focused along a focal axis and diverging when viewed perpendicular to the focal axis.

64. (previously added) The method of claim 61, further comprising the step of: moving a focus of the focused ultrasound relative to the cardiac tissue.

65. (previously added) The method of claim 64, wherein: the moving step is carried out to move the focus closer to a near surface of the cardiac tissue.

66. (currently canceled)

67. (previously added) The method of claim 61, wherein: the providing step is carried out with the focused energy being emitted by a concave surface.

68. (currently amended) The method of claim 67, wherein: the providing step is carried out with the concave surface being attached to a piezoelectric transducer.

69. (previously added) The method of claim 67, wherein:

the providing step is carried out with the concave surface having a focal length of 2-20 mm.

70. (previously added) The method of claim 69, wherein:  
the providing step is carried out with the focused energy having a focal length of 2 to 12 mm.

71. (previously added) The method of claim 61, wherein:  
the activating step is carried out by activating the ultrasonic transducer for a first period of time at a first frequency and a second period of time at a second frequency which is different than the first frequency and occurs after the first period of time.

72. (previously added) The method of claim 71, wherein:  
the activating step is carried out with the first frequency being lower than the second frequency.

73. (previously added) The method of claim 72, wherein:  
the activating step is carried out with the first period of time being shorter than the second period of time.

74. (previously added) The method of claim 73, wherein:  
the activating step is carried out with the first period of time being less than 1 second.

75. (previously added) The method of claim 71, wherein:  
the activating step is carried out with the ultrasonic transducer being activated at the first frequency for a number of discrete time periods.

76. (previously added) The method of claim 75, wherein:  
the activating step is carried out with the ultrasonic transducer being inactive for 3-8 seconds between each of the number of discrete time periods.

77. (previously added) The method of claim 61, further comprising the step of:  
approximating a temperature of the tissue.

78. (previously added) The method of claim 61, further comprising the step of:  
assessing the adequacy of contact between the device and the tissue.

79. (previously added) The method of claim 61, further comprising the step of:  
determining a tissue layer thickness using the ultrasound transducer.

80. (previously added) The method of claim 79, wherein:  
the determining step is carried out with the tissue layer being a tissue layer between a near surface and a far surface.

81. (previously added) The method of claim 79, wherein:

the determining step is carried out with the tissue layer being a fat layer which lies over a muscle layer.

82. (previously added) The method of claim 61, further comprising the step of: measuring a blood flow velocity with the ultrasonic transducer.

83. (previously added) The method of claim 61, further comprising the step of: moving the a focus of the focused ultrasound relative to the tissue.

84. (previously added) The method of claim 83, wherein: the moving step is carried out with the ultrasonic transducer being tilted.

85. (previously added) The method of claim 61, wherein: the providing step is carried out with the ablating device having a number of ultrasonic transducers.

91. (currently amended) The method of claim 61, further comprising the step of: assessing the contact between the ablating device and the tissue structure.

92. (previously added) The method of claim 91, wherein: the assessing step is carried out by measuring the electrical impedance.

93. (currently amended) The method of claim 61, further comprising: measuring a tissue thickness using the ultrasonic transducer, the ultrasonic transducer emitting ultrasound energy and receiving ultrasound energy reflected from a far surface of the tissue structure.

94. (currently amended) The method of claim 61, further comprising the step of: measuring a fat thickness using the ultrasonic transducer, the ultrasonic transducer emitting ultrasound energy and receiving ultrasound energy reflected from a boundary between fat and muscle.

003-007 C3  
Appln. No. 10/006,064  
John W. Sliwa et al.  
Filed December 5, 2001  
Title: METHODS AND DEVICES FOR ABLATION

(Please note: the following claims will be renumbered in an official amendment.)

80. A device for ablating tissue, comprising:  
a body having a longitudinal axis and a contact surface configured to be positioned adjacent tissue to be ablated;  
a first transducer coupled to the body;  
a second transducer coupled to the body and spaced apart from the first transducer by a space;  
a first flexible membrane which extends over the first transducer, the first flexible membrane conforming to the surface of the tissue and being filled with a substance which transmits the ultrasound energy from the first transducer to the tissue when the first flexible membrane is in contact with the tissue; and  
a second flexible membrane which extends over the second transducer, the second flexible membrane conforming to the surface of the tissue and being filled with a substance which transmits the ultrasound energy from the second transducer to the tissue when the second flexible membrane is in contact with the tissue;  
wherein both of the first and second transducers direct focused ultrasound energy to tissue lying beneath the space between the first and second transducers.

81. The device of claim 80, wherein:  
the first and second transducers have the same shape, the first and second transducers each directing ultrasound energy to the tissue beneath the first and second transducers, respectively, and to the tissue lying beneath the space between the first and second transducers.

82. The device of claim 80, wherein:  
a plurality of the transducers are positioned around the body to create a continuous, closed-loop lesion.



003-007 C4

Appln. No. 10/008,997

John W. Sliwa et al.

Filed December 5, 2001

Title: METHODS AND DEVICES FOR ABLATION

61. A method of ablating a cardiac tissue, comprising the steps of:  
providing an ablating device having a first transducer and a second transducer;  
positioning the ablating device against cardiac tissue;  
activating the first transducer at a first frequency to ablate cardiac tissue; and  
activating the second transducer at a second frequency to ablate cardiac tissue.

62. The method of claim 61, further comprising the step of:  
moving the ablating device so that the activating steps are carried out to ablate the same cardiac tissue.

63. The method of claim 61, wherein:  
the activating steps are carried out to ablate different cardiac tissue.

64. The method of claim 61, further comprising:  
characterizing at least a portion of the cardiac tissue; and  
selecting at least one of the first and second transducers to ablate the at least portion of the cardiac tissue based upon the characterizing step.

65. A method of ablating a cardiac tissue, comprising the steps of:  
providing an ablating device having a first transducer and a second transducer, the first and second transducers both being focused, the first and second transducers having different focal lengths;  
positioning the ablating device against cardiac tissue;  
activating the first transducer to ablate cardiac tissue; and  
activating the second transducer.

66. The method of claim 65, wherein:  
the providing step is carried out with the first transducer having a first focal length and the second transducer has a second focal length different than the first focal length.

67. The method of claim 65, wherein:  
the providing step is carried out with the ablating device having a body, the first and second transducers being movable along the body.

68. The method of claim 67, wherein:  
the providing step is carried out with the first and second transducers being slidable along the body.

68. The method of claim 67, further comprising the step of:

positioning the body at a selected location on an epicardial surface; and moving the first and second transducers after the positioning step.

70. A device for ablating tissue, comprising:  
a body;  
a source of focused ultrasound mounted to the body, the focused ultrasound having a focus; and  
a flexible membrane filled with a substance which receives the focused ultrasound and transmits the ultrasound energy to the tissue.

71. The device of claim 70, wherein:  
the flexible membrane is inflatable to move the focus relative to the tissue to be ablated.

72. The device of claim 70, wherein:  
the flexible membrane tilts the body when inflated.

73. The device of claim 70, wherein:  
the source of focused ultrasound includes an ultrasound transducer.

74. A system for ablating tissue with ultrasound energy, comprising:  
an ablating element which emits ultrasound energy;  
a control system coupled to the ablating element, the control system controlling activation of the ablating element to automatically change a characteristic of the ablating element when ablating the same tissue structure during a first time period and a second time period.

75. The system of claim 74, wherein:  
the control system is configured to automatically change a frequency of the ablating element.

76. The system of claim 74, wherein:  
the control system is configured to automatically change the power of the ablating element.

77. The system of claim 74, wherein:  
the ablating element emits focused ultrasound which is focused in at least one direction.

78. The system of claim 74, wherein:  
the control system automatically moves the focus relative to the tissue structure being ablated.

79. The system of claim 77, wherein:  
the control system moves the focus closer to a near surface of the tissue structure being ablated.

80. The method of claim 74, wherein:

the control system includes means for assessing the adequacy of contact between the device and the tissue structure being ablated.

81. The method of claim 78, wherein:  
the assessing means is carried out by measuring an electrical impedance.

Appl. No. : 10/008,997  
Applicant : SLIWA et al.  
Filed : December 5, 2001  
Title : METHODS AND DEVICES FOR ABLATION  
TC/A.U. : 3739  
Examiner : Michael F. Peffley  
Docket No. : 003-007-C4

74. A system for ablating tissue with ultrasound energy, comprising:  
a plurality of ablating elements which each emit focused ultrasound  
energy; and

a control system coupled to the ablating elements, the control system  
controlling activation of the ablating elements and adapted to automatically change the  
frequency of the ablating elements when ablating the same tissue structure, each ablating  
element being activated to ablate tissue at a first frequency for a first plurality of time  
periods and to ablate the same tissue at a second frequency, which is different than the  
first frequency, for a second plurality of time periods.

75-77. (Canceled)

78. (Currently Amended) The system of claim 74, wherein:  
the control system is adapted to move a focus of the ultrasound energy  
relative to the tissue structure being ablated.

79. (Currently Amended) The system of claim 78, wherein:  
the control system moves the focus closer to a near surface of the tissue  
structure being ablated.

80. (Currently Amended) The method of claim 74, wherein:  
the control system includes means for assessing the adequacy of contact  
between the ablating elements and the tissue structure being ablated.

81. (Previously added) The method of claim 78, wherein:  
the assessing means is carried out by measuring an electrical impedance.

- 1                   1.       A method of ablating tissue, comprising the steps of:  
2                   providing an ablation device having an ablating element;  
3                   positioning the ablating device against a target tissue;  
4                   emitting energy from an emitter so that the energy passes through the target tissue;  
5                   measuring the energy which passes through the target tissue with a receiver; and  
6                   ablating the target tissue with the ablating element.
- 1                   2.       The method of claim 1, wherein:  
2                   the ablating step is carried out by placing the ablating device at an epicardial location, the ablating  
3                   step being carried out to electrically isolate a portion of the heart.
- 1                   3.       The method of claim 1, wherein at least one of the emitting and measuring steps is  
2                   carried out with the ablating element.
- 1                   4.       The method of claim 1, wherein the emitting step is carried out with the ablating element.
- 1                   5.       The method of claim 1, wherein the emitting step is carried out intermittently when the  
2                   ablating step is temporarily stopped.
- 1                   6.       The method of claim 1, wherein the measuring step is carried out with the ablating  
2                   element.
- 1                   7.       The method of claim 1, wherein the measuring step is carried out intermittently when the  
2                   ablating step is temporarily stopped.
- 1                   8.       The method of claim 1, wherein:  
2                   the measuring step is carried out by measuring the amount of energy received at the receiver.
- 1                   9.       The method of claim 1, further comprising the step of:  
2                   indicating a change in the characteristic of the energy to the user.
- 1                   10.      The method of claim 9, wherein:  
2                   the indicating step is carried out by indicating a decrease in energy magnitude transmitted through  
3                   the target tissue.
- 1                   11.      The method of claim 9, wherein:  
2                   the indicating step is carried out with the characteristic of the energy including frequency.
- 1                   12.      The method of claim 1, wherein:  
2                   the providing step is carried out with an intravascular device;  
3                   introducing the intravascular device into the patient's vascular system;  
4                   wherein at least one of the emitting and measuring steps are carried out with the intravascular  
5                   device.
- 1                   13.      The method of claim 1, wherein:  
2                   the measuring step is carried out with the ablating elements being the receiver.
- 1                   14.      The method of claim 1, wherein:  
2                   the emitting step is carried out by emitting ultrasound energy.

15. The method of claim 1, wherein:  
the emitting step is carried out by emitting energy from the ablating element; and  
the measuring step is carried out by receiving energy at a plurality of receivers.

16. The method of claim 1, wherein:  
the providing step is carried out with the ablating device having a plurality of ultrasound ablating elements; and  
the emitting and measuring steps are carried out by emitting and measuring the energy with the plurality of ultrasound ablating elements.

17. The method of claim 1, wherein:  
the providing step is carried out with the ablating device forming a closed loop; and  
the positioning step is carried out to form the closed loop around a portion of the heart.

18. The method of claim 1, wherein:  
the emitting and ablating steps are carried out at the same time with the energy being used to ablate the target tissue.

19. The method of claim 1, wherein:  
the providing step is carried out with the ablating element being an ultrasound element; and  
the emitting step is carried out with the ultrasound energy being different than the ablating step.

20. The method of claim 1, wherein:  
the providing step is carried out with the ablating element producing focused ultrasound.

21. A device for ablating a target tissue, comprising:  
a plurality of ablating elements;  
an emitter which emits energy toward the target tissue;  
a receiver which receives energy transmitted through the target tissue;  
a control system coupled to the ablating elements, the emitter, and the receiver, the control system determining a change in an energy characteristic of the energy transmitted from the emitter to the receiver.

22. The device of claim 21, wherein:  
the control system has an indicator which indicates the energy characteristic, the indicator providing the user with an indication of a change in the energy characteristic.

23. The device of claim 21, wherein:  
at least one of the ablating element acts as the receiver.

24. The device of claim 21, wherein:  
the control system controls the ablating element to stop emitting ablating energy while receiving energy transmitted through the target tissue from the emitter.

25. The device of claim 21, wherein:  
at least one of the ablating elements acts as the emitter.

26. The device of claim 25, wherein:  
the control system controls the ablating element to emit ablating energy which is different than energy emitted which is received by the receiver.

27. The device of claim 21, wherein:  
at least one of the ablating element acts as the receiver.  
at least one of the ablating elements acts as the emitter.

1 28. The device of claim 21, wherein:  
2 the indicator provides an indication of the magnitude of the energy received by the receiver.

1 29. The device of claim 21, wherein:  
2 the indicator provides an indication of the frequency of the energy passing through the target  
3 tissue.

1 30. The device of claim 21, further comprising:  
2 an intravascular device which acts as at least one of the emitter and receiver.

1 31. A method of ablating cardiac tissue, comprising the steps of:  
2 providing an ablating device having at least one ablating element, the ablating element having a  
3 focus;  
4 positioning the ablating device on a epicardial surface, wherein the focus is positioned at an angle  
5 with respect to the epicardial surface; and  
6 ablating tissue with the ablating element with the device positioned on the epicardial surface to  
7 form a first lesion.

1           1.       A method of ablating tissue, comprising the steps of:  
2           providing an ablation device having an ablating element;  
3           positioning the ablating device against a target tissue;  
4           emitting energy from an emitter so that the energy passes through the target tissue;  
5           measuring the energy which passes through the target tissue with a receiver; and  
6           ablating the target tissue with the ablating element.

1           2.       The method of claim 1, wherein:  
2           the ablating step is carried out by placing the ablating device at an epicardial location, the ablating  
3           step being carried out to electrically isolate a portion of the heart.

1           3.       The method of claim 1, wherein at least one of the emitting and measuring steps is  
2           carried out with the ablating element.

1           4.       The method of claim 1, wherein the emitting step is carried out with the ablating element.

1           5.       The method of claim 1, wherein the emitting step is carried out intermittently when the  
2           ablating step is temporarily stopped.

1           6.       The method of claim 1, wherein the measuring step is carried out with the ablating  
2           element.

1           7.       The method of claim 1, wherein the measuring step is carried out intermittently when the  
2           ablating step is temporarily stopped.

1           8.       The method of claim 1, wherein:  
2           the measuring step is carried out by measuring the amount of energy received at the receiver.

1           9.       The method of claim 1, further comprising the step of:  
2           indicating a change in the characteristic of the energy to the user.

1           10.      The method of claim 9, wherein:  
2           the indicating step is carried out by indicating a decrease in energy magnitude transmitted through  
3           the target tissue.

1           11.      The method of claim 9, wherein:  
2           the indicating step is carried out with the characteristic of the energy including frequency.

1           12.      The method of claim 1, wherein:  
2           the providing step is carried out with an intravascular device;  
3           introducing the intravascular device into the patient's vascular system;  
4           wherein at least one of the emitting and measuring steps are carried out with the intravascular  
5           device.

1           13.      The method of claim 1, wherein:  
2           the measuring step is carried out with the ablating elements being the receiver.

1           14.      The method of claim 1, wherein:



2 the emitting step is carried out by emitting ultrasound energy.

1 15. The method of claim 1, wherein:  
2 the emitting step is carried out by emitting energy from the ablating element; and  
3 the measuring step is carried out by receiving energy at a plurality of receivers.

1 16. The method of claim 1, wherein:  
2 the providing step is carried out with the ablating device having a plurality of ultrasound ablating  
3 elements; and  
4 the emitting and measuring steps are carried out by emitting and measuring the energy with the  
5 plurality of ultrasound ablating elements.

1 17. The method of claim 1, wherein:  
2 the providing step is carried out with the ablating device forming a closed loop; and  
3 the positioning step is carried out to form the closed loop around a portion of the heart.

1 18. The method of claim 1, wherein:  
2 the emitting and ablating steps are carried out at the same time with the energy being used to  
3 ablate the target tissue.

1 19. The method of claim 1, wherein:  
2 the providing step is carried out with the ablating element being an ultrasound element; and  
3 the emitting step is carried out with the ultrasound energy being different than the ablating step.

1 20. The method of claim 1, wherein:  
2 the providing step is carried out with the ablating element producing focused ultrasound.

1 21. A device for ablating a target tissue, comprising:  
2 a plurality of ablating elements;  
3 an emitter which emits energy toward the target tissue;  
4 a receiver which receives energy transmitted through the target tissue;  
5 a control system coupled to the ablating elements, the emitter, and the receiver, the control system  
6 determining a change in an energy characteristic of the energy transmitted from the emitter to the receiver.

1 22. The device of claim 21, wherein:  
2 the control system has an indicator which indicates the energy characteristic, the indicator  
3 providing the user with an indication of a change in the energy characteristic.

1 23. The device of claim 21, wherein:  
2 at least one of the ablating element acts as the receiver.

1 24. The device of claim 21, wherein:  
2 the control system controls the ablating element to stop emitting ablating energy while receiving  
3 energy transmitted through the target tissue from the emitter.

1 25. The device of claim 21, wherein:  
2 at least one of the ablating elements acts as the emitter.

1 26. The device of claim 25, wherein:  
2 the control system controls the ablating element to emit ablating energy which is different than  
3 energy emitted which is received by the receiver.

1 27. The device of claim 21, wherein:  
2 at least one of the ablating element acts as the receiver.  
3 at least one of the ablating elements acts as the emitter.

- 1 28. The device of claim 21, wherein:  
2 the indicator provides an indication of the magnitude of the energy received by the receiver.
- 1 29. The device of claim 21, wherein:  
2 the indicator provides an indication of the frequency of the energy passing through the target  
3 tissue.
- 1 30. The device of claim 21, further comprising:  
2 an intravascular device which acts as at least one of the emitter and receiver.
- 1 31. A method of ablating cardiac tissue, comprising the steps of:  
2 providing an ablating device having at least one ablating element, the ablating element having a  
3 focus;  
4 positioning the ablating device on a epicardial surface, wherein the focus is positioned at an angle  
5 with respect to the epicardial surface; and  
6 ablating tissue with the ablating element with the device positioned on the epicardial surface to  
7 form a first lesion.
- 1 32. The method of claim 31, wherein:  
2 the positioning step is carried out with the focus being angled with respect to the epicardial surface  
3 so that the focus extends through a substantial portion of the thickness of the target tissue.
- 1 33. The method of claim 31, wherein:  
2 the positioning step is carried out with the focus being angled with respect to the epicardial surface  
3 so that the focus extends through the entire thickness of the target tissue.
- 1 34. The method of claim 31, wherein:  
2 the providing step is carried out with the angle of the ablating element being adjustable so that the  
3 angle of the focus relative to the target tissue may be varied.
- 1 35. The method of claim 31, further comprising the step of:  
2 moving the ablating element; and  
3 ablating tissue again after the moving step to form a second lesion continuous with the first lesion.
- 1 36. The method of claim 31, wherein:  
2 the moving step is carried out with the ablating element continuing to ablate tissue.
- 1 37. The method of claim 31, wherein:  
2 the moving step is carried out by moving the ablating device across the epicardial surface.
- 1 38. The method of claim 31, wherein:  
2 the providing step is carried out with the ablating device being coupled to a guide member; and  
3 the moving step is carried out with the ablating device being moved relative to the guide member.
- 1 39. The method of claim 38, further comprising:  
2 positioning the guide member at a fixed position relative to the target tissue;  
3 the moving step being carried out a number of times with the guide member being at the fixed  
4 position.
- 1 40. The method of claim 31, wherein:  
2 the providing step is carried out with the ablating element producing focused ultrasound.
- 1 41. A device for ablating tissue, comprising:  
2 a shaft; and

3 a plurality of ablating elements coupled to the shaft, the plurality of ablating elements being  
4 configured to produce a continuous lesion in a target tissue.

1 42. The device of claim 41, wherein:  
2 the plurality of ablating elements are focused ultrasound ablating elements.

1 43. The device of claim 41, further comprising:  
2 at least two electrodes on a bottom side of the plurality of ablating elements.

1 44. The device of claim 41, further comprising:  
2 a control system coupled to the plurality of ablating elements, the control system controlling the  
3 ablating elements.

1 45. The device of claim 41, wherein:  
2 the shaft has a rigid portion and a flexible portion at a distal end of the rigid portion, the flexible  
3 portion having a coil covered by a flexible sheath, the distal portion being deformable.

1 46. A method of ablating cardiac tissue, comprising the steps of:  
2 providing an ablating device having at least one ablating element;  
3 positioning the ablating device on a epicardial surface;  
4 ablating tissue with the ablating element with the device positioned on the epicardial surface to  
5 form a first lesion;  
6 moving the ablating element to a new position; and  
7 ablating tissue to form a second lesion at the new position which is continuous with the first  
8 lesion.

1 47. The method of claim 46, wherein:  
2 the moving step is carried out with an inflatable element.

1 48. The method of claim 46, wherein:  
2 the moving step is carried out with the ablating element continuing to ablate tissue while moving  
3 the ablating element.

1 49. The method of claim 46, wherein:  
2 the moving step is carried out by moving the ablating device along the epicardial surface.

1 50. The method of claim 46, wherein:  
2 the providing step is carried out with the ablating device being coupled to a guide member; and  
3 the moving step is carried out with the ablating device being moved relative to the guide member.

1 51. The method of claim 50, further comprising the step of:  
2 positioning the guide member at a fixed position relative to the target tissue;  
3 the moving step being carried out a number of times with the guide member being at the fixed  
4 position.

1 52. The method of claim 50, wherein:  
2 the providing step is carried out with the guide member being a tube.

1 53. The method of claim 52, wherein:  
2 the providing step is carried out with the tube having an opening; and  
3 the positioning step is carried out with the ablating element positioned to emit energy through the  
4 opening.

1 54. The method of claim 53, wherein:  
2 the providing step is carried out with the ablating element being a laser.

1                    55.        The method of claim 46, wherein:  
2                    the providing step is carried out with the ablating element having a focus; and  
3                    the positioning step is carried out with the focus being angled with respect to the epicardial surface  
4                    so that the focus extends through at least a substantial portion of the thickness of the target tissue.

1                    56.        The method of claim 46, wherein:  
2                    the positioning step is carried out with the focus being angled with respect to the epicardial surface  
3                    so that the focus extends through the entire thickness of the target tissue.

1                    57.        The method of claim 46, wherein:  
2                    the providing step is carried out with the ablating element producing focused ultrasound.

1                    58.        The method of claim 46, wherein:  
2                    the moving step is carried out by moving the ablating element toward or away from the epicardial  
3                    surface.

4                    59.        The method of claim 46, wherein:  
5                    the moving step is carried out by moving the ablating element along an arc above the epicardial surface.

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Title: METHODS AND DEVICES FOR ABLATION

80. A device for ablating tissue, comprising:  
a body;  
a first ablating element coupled to the body, the first ablating element emitting focused ultrasound energy having a focal length of 2-20 mm, the focused ultrasound energy being focused in at least one direction;  
a second ablating element coupled to the body, the second ablating element emitting focused ultrasound energy having a focal length of 2-20 mm, the focused ultrasound energy being focused in at least one direction; and  
a control system which automatically activates the first and second ablating elements each for a first plurality of time periods at a first frequency and a second plurality of time periods at a second frequency which is different than the first frequency.

81. The device of claim 80, wherein:  
the second ablating element has a different focal length than the first ablating element.

82. The device of claim 80, further comprising:  
means for moving a focus of the focused ultrasound relative to the tissue.

83. The device of claim 80, wherein:  
the first and second ablating elements have a focal length of 2 to 12 mm.

84. The device of claim 80, wherein:  
the control system deactivates the first and second ablating elements, respectively, between each of the first and second plurality of time periods.

85. The device of claim 84, wherein:  
the control system deactivates the first and second ablating elements for 5-80 seconds between each of the first and second plurality of time periods.

86. The system of claim 80, wherein:  
the control system changes at least one of a frequency, power, period of time and location of the focus relative to the tissue for the first and second ablating elements.

87. The system of claim 80, wherein:  
the control system increases the frequency from the first frequency to the second frequency.

88. The system of claim 80, further comprising:  
means for assessing the contact between the ablating device and the tissue structure.

89. The system of claim 80, further comprising:  
means for measuring a tissue thickness using the ultrasonic transducer.

90. The system of claim 80, wherein:  
the first and second transducers are slidably movable along the body.